

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|--------------------------------------|----------------------|---------------------|------------------|
| 10/562,269 | 02/12/2007 | Gary E. Gilbert | US 1451/05 (BWH) | 7866 |
| | 7590 10/30/200 ineshAgarwal. P.C. | EXAMINER | | |
| 5350 Shawnee Road | | | GITOMER, RALPH J | |
| Suite 330 Alexandria, VA | . 22312 | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/30/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|----------------|--|--|--|--|
| | 10/562,269 | GILBERT ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Ralph Gitomer | 1657 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 14 Se | eptember 2009. | | | | | |
| • | action is non-final. | | | | | |
| <i>,</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| • 4)⊠ Claim(s) <u>1-27</u> is/are pending in the application. | | | | | | |
| ,— , , , — , , , , , , , , , , , , , , | 4a) Of the above claim(s) <u>9-18 and 21-25</u> is/are withdrawn from consideration. | | | | | |
| 5)⊠ Claim(s) <u>1-8</u> is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>.18-,20,26 and 27</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| · · · <u> </u> | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some coll None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | о п | (DTO 440) | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

The amendment and Declaration received 9/14/09 have been entered and claims 1-8, 18-20, 26-27 are considered here. The amended title and abstract are acceptable.

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In view of the Declaration, amendments to the claims and arguments presented the rejections of record under 35 USC 102(a) and 112, second paragraph, are hereby withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-20, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert.

Art Unit: 1657

Albert (2006/0257431) entitled "Methods for use of Apoptotic Cells to Deliver Antigen to Dendritic Cells for Induction or Tolerization of T Cells" teaches in paragraph 196 that lactadherin is a major glycoprotein of the human milk fat globule membrane.

Claims 18-20 differ from Albert in that they are directed to a kit, claims 26-27 are directed to a probe.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ lactadherin in the presently claimed kit and probe because Albert teaches that lactadherin is found in human milk, a product of nature, and the claims as presented read on simply lactadherin. Many of the references cited herein describe a purified and isolated lactadherin and kits and probes are well known in the assay art.

Applicant's arguments filed 9/14/09 have been fully considered but they are not persuasive.

Applicants response argues that Albert merely believes and suggests the teachings regarding lactadherin activity which amounts to speculation.

It is the examiner's position that, at the least, Albert provides an invitation to try which renders obvious the present claims directed to a kit and probe which read on lactadherin, a known substance. The intended use of the kit and probe are given little or no patentable weight.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Step (c) in claim 1 is directed to binding.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/ Primary Examiner, Art Unit 1657 Ralph Gitomer Primary Examiner Art Unit 1657